

REMARKS

Claims 1-48 are pending in this application. Claims 32 and 34 have been canceled and claims 1-28 and 35-48 have been withdrawn, leaving claims 29, 31, and 33 remaining. Claims 32 and 34 have been canceled in the expectation that the amendments will place this application in condition for allowance. The subject matter of canceled claims 32 and 34 have been incorporated into the independent claim 29, from which they depend. Claims 29, 31, and 33 have been amended.

The amendments do not introduce new matter within the meaning of 35 U.S.C. §132. Basis for the claim amendments is found in claims 1-48 as originally filed, and elsewhere throughout the specification and claims. Accordingly, entry of the amendments is respectfully requested.

1. Objections to the Claims

The Office Action objects to the claims because of the following informalities:

Claims 31 and 33 are objected to because of the use of "SEQ. ID NO.". Use of "SEQ ID NO:" is suggested.

Applicants thank the Examiner for her comments, and have amended claims 31 and 33 as suggested.

Accordingly, Applicants respectfully request the Examiner to reconsider and withdraw the objections to the claims.

**2. Rejection of Claims 29 and 31-34 under 35 U.S.C. §112,
second paragraph**

The Office Action rejects claims 29 and 31-34 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for the following reasons:

Claims 29 and 31-34 are indefinite because the claims lack an essential step in the method of effectuating antitumor activity in animals. The omitted step is the outcome for the treatment. Claims 31-34 are included in this rejection for being dependent on a rejected claim and not correcting the deficiency of the claim from which they depend.

* * *

Claims 29 and 31-34 are indefinite because of the use of the term "and/or". The term "and/or" renders the claim indefinite, it is unclear whether the limitation after "and/or" is included or not, and if included is to be read as an alternative "or" or the conjunctive "and".

Applicants thank the Examiner for her helpful comments. Applicants have amended claim 29 essentially as suggested by the Examiner, to claim a clearly defined end step of the inventive methods, while retaining the disclosed scope of the inventive subject matter. Applicants have also amended claim 29 to clearly indicate that "and/or" refers to *both* the conjunctive and disjunctive, and that the claims are not limited to one result, but also encompass the situation where multiple results are achieved by the inventive methods.

Accordingly, Applicants respectfully request the Examiner to reconsider and withdraw the rejection of claims 29, 31, and 33.

3. Rejection of Claim 29 under 35 U.S.C. §102

The Office Action rejects claim 29 under 35 U.S.C. §102(b), as being anticipated by Applicants earlier publication, Yoon, et al. (International J. Immunopharmacology 20, 163-172 (April-May 1998)), for the reasons that:

Yoon et al. teach an extract (KM-110) prepared from *Viscum album coloratura* (Korean mistletoe) inhibits tumor metastasis in experimental lung metastasis of B16-BL6 melanoma or colon 26-M3.1 carcinoma cells (Table 1), and spleen metastasis of L5178Y-ML25 lymphoma cells (Table 2) when administered of KM-110 (100 µg) to mice before tumor inoculation (pages 166-167; claim 29). Claim 29 is anticipated by the reference because the extract of KM-110 prepared from Korean mistletoe contains isolated lectins as shown in the specification and has antitumor activity, and claim 29 recites the lectin of KML-IIU or KML-IIL, but, no characteristic or property of the protein is indicated, thus any lectin having antitumor activity and isolated from Korean mistletoe is considered as KML-IIU or KML-IIL.

Applicants respectfully traverse this rejection on the basis that Yoon, et al. fails to teach the claimed subject matter, as amended. As the Examiner admits, Yoon, et al. teaches the use of KM-110. As amended, pending claims 29, 31, and 33 relate to KML-IIU and KML-IIL. As amended, claim 29 incorporates the limitations of canceled claims 32 and 34, specifically the molecular weights of KML-IIU and KML-IIL. Clearly, as the Examiner

has already conceded by the indication that claims 31-34 are not rejected over Yoon, et al., KML-IIU and KML-IIL as claimed are not the same as KM-110; KM-110 is a crude extract of Korean mistletoe, while KML-IIU and KML-IIL are isolated and specifically described lectins. Yoon, et al. does not even mention the presence of any lectin(s) in KM-110, let alone the specific lectins, KML-IIU, having a molecular weight of 61.8 kD, and KML-IIL, having a molecular weight of 56.4 kD. Thus, the Examiner's conclusion that "any lectin having antitumor activity and isolated from Korean mistletoe is considered as KML-IIU or KML-IIL," is unsupported by the disclosure in the cited reference and contradicted by claim 29 as amended.

To constitute anticipation under 35 U.S.C. §102, all material elements of a claim must be found in one prior art source. In re Marshall, 577 F.2d 301, 198 USPQ 344 (CCPA 1978); In re Kalm, 378 F.2d 959, 154 USPQ 10 (CCPA 1967). Yoon's disclosure of KM-110 is not tantamount to a disclosure of isolated KML-IIU, having a molecular weight of 61.8 kD, or KML-IIL, having a molecular weight of 56.4 kD. Thus, in the absence of any teaching in Yoon, et al. that KM-110 would necessarily lead one to KML-IIU, KML-IIL, or both, Yoon, et al. does not anticipate the present claims.

Accordingly, Applicants respectfully request the Examiner to reconsider and withdraw the rejection of claim 29.

4. Rejection of Claims 29 under 35 U.S.C. §103

The Office Action rejects claim 29 under 35 U.S.C. §103, as being unpatentable over Khwaja et al. (Proc. Am. Assoc. Cancer Res. Annu. Meet. 28, 303 (1987)) taken with Khwaja (U. S. Patent 5,565,200), for the reasons that:

Khwaja et al. Khwaja et al. teach a lectin, which is isolated from the aqueous extract of Viscum album, Coloratura (Korean mistletoe) by precipitation with 70% ammonium sulfate, absorbing on Sepharose 4B column, and eluting with 0.15 M lactose in 0.5 M NaCl, has anticancer activity against the growth of leukemia L1210 cells in culture with IC50 of 0.66 ng/ml, and the SDS gel electrophoresis of lectin shows two major bands 29 and 36 kDa (whole abstract). However, Khwaja et al. do not disclose the administration of the lectin to an animal. Khwaja teaches aqueous extracts from Korean mistletoe, which contain lectins, viscotoxins and alkaloidal compounds, exhibit antileukemia activity against L1210 cells and anticancer activity in animals bearing tumor cells (column 11, line 57-column 12, line 35; Example 1; claim 12 of the '200 patent). At the time of invention was made, it would have been obvious to one of ordinary skill in the art to use the isolated lectin taught by Khwaja et al. in treating an animal having cancer because the use of an active ingredient in the extract would provide an alternative method for effective treatment of cancer. Thus, the combined references result in the claimed invention and was, as a whole, prima facie obvious at the time the claimed invention was made. Claim 29 recites the lectin of KML-IIU or KML-IIL, but, no characteristic or property of the protein is indicated, thus any lectin having antitumor activity and isolated from Korean mistletoe is considered as KML-IIU or KML-IIL.

Applicants respectfully traverse this rejection. As the Examiner admits, Khwaja, et al. teaches the use of two lectins characterized as having major bands at 29 kDa and 36 kDa. Khwaja,

et al. is deficient in teaching the inventive subject matter because it does not disclose KML-IIU, having a molecular weight of 61.8 kD, or KML-IIL, having a molecular weight of 56.4 kD, properties which are clearly distinguishable from either Khwaja, et al. or the Khwaja patent. Thus, contrary to the Examiner's conclusion that "any lectin having antitumor activity and isolated from Korean mistletoe is considered as KML-IIU or KML-IIL," the claims as amended relate to lectins which are clearly distinguishable over the cited art of record.

To establish a *prima facie* case, the PTO must satisfy three requirements. First, the prior art reference must teach or suggest all the limitations of the claims. *In re Wilson*, 424 F.2d 1382, 1385, 165 U.S.P.Q. 494, 496 (C.C.P.A. 1970). Second, the prior art relied upon, coupled with the knowledge generally available in the art at the time of the invention, must contain some suggestion or incentive that would have motivated the skilled artisan to modify a reference. *In re Fine*, 837 F.2d 1071, 1074, 5 U.S.P.Q.2d 1596, 1598 (Fed. Cir. 1988). Lastly, the proposed modification of the prior art must have had a reasonable expectation of success, determined from the vantage point of the skilled artisan at the time the invention was made. *Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1209, 18 U.S.P.Q.2d 1016, 1023 (Fed. Cir. 1991).

The cited references meet none of these requirements. Neither Khwaja, et al. nor the Khwaja patent, alone or in combination, teach or suggest isolated KML-IIU, having a molecular weight of 61.8 kD, or KML-IIL, having a molecular weight of 56.4 kD. Lacking this element of Applicants' claims, there is no teaching of the inventive subject matter. Lacking a teaching of the inventive subject matter in the cited references, alone or in combination, there clearly is no motivation to modify the teaching of either cited reference to produce the inventive subject matter. Nor is there a reasonable expectation of success without the required teaching of the molecular weight of either KML-IIU or KML-IIL, or some motivation to modify Khwaja, et al. or the Khwaja patent to use KML-IIU or KML-IIL. Thus, in the absence of any teaching or suggestion in Khwaja, et al. or the Khwaja patent that KML-IIU or KML-IIL would be useful for treating tumors, the claims of the present application cannot be obvious over Khwaja, et al. or the Khwaja patent, either alone or in combination.

Accordingly, Applicants respectfully request the Examiner to reconsider and withdraw the rejection of claim 29.

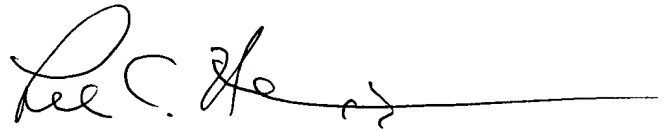
CONCLUSION

Based upon the above remarks, the presently claimed subject matter is believed to be novel and patentably distinguishable over the prior art of record. The Examiner is therefore respectfully requested to reconsider and withdraw the rejections of remaining claims 29-34, and to allow pending claims 29, 31, and 33 presented herein for reconsideration. Favorable action with an early allowance of the claims pending in this application is earnestly solicited.

The Examiner is welcomed to telephone the undersigned attorney if she has any questions or comments.

Respectfully submitted,

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